DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 5, 2015

Pioneer Surgical Technology, Inc.
Sarah Pleaugh
Regulatory Affairs Specialist
375 River Park Circle
Marquette, MI 49855 USA

Re: K142438
Trade/Device Name: Nerve Monitoring Cable System
Regulation Number: 21 CFR 874.1820
Regulation Name: Neurosurgical Nerve Locator
Regulatory Class: Class II
Product Code: PDQ, ETN, GXZ
Dated: January 30, 2015
Receive: February 2, 2015

Dear Ms. Pleaugh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142438

Device Name
Nerve Monitoring Cable System

Indications for Use *(Describe)*
The Nerve Monitoring Cable in conjunction with dilators, pedicle probes, taps, awls or screw drivers, are intended for tissue dilation/dissection and stimulation of peripheral nerves including spinal nerve roots for location and identification during spinal surgery.

The dilators are also intended for use in surgical procedures to provide surgical access by dilating the soft tissue to the intended surgical site to allow passage of current from a point on the proximal end to an uninsulated portion of the distal tip. The purpose of this is to allow controlled monitoring of neural elements near and around the point of access. The dilators are offered sterile/single use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary Pursuant to 21 CFR 807.92

K142438

510(k) Owner:	Pioneer Surgical Technology, Inc. (RTI Surgical, Inc.) 375 River Park Circle Marquette, MI 49855 USA Ph.: (906) 225-5861 Fax: (906) 226-4459 Contact: Sarah (McIntyre) Pleaugh Prepared: January 30, 2015
Trade name:	Nerve Monitoring Cable System
Common name:	Neurosurgical Nerve Locator
Classification:	Class II; 21 CFR 874.1820, PDQ, Neurosurgical nerve locator and ETN, Nerve stimulator 21 CFR 882.1350, GXZ, Needle electrode
Predicate Devices:	K073229 Pioneer Surgical Technology, Inc. - Nerve Monitoring Cable System K132373 Biomet Spine - Biomet Probes/Guidewires and Dilators K140400 Stryker Spine - ES2® Neuromonitoring Accessory Instruments
Device Description:	The Nerve Monitoring Cable System, which consists of Nerve Monitoring Cables in conjunction with various stimulation accessories, allow for tissue dilation and stimulation of peripheral nerve roots for location and identification during open and percutaneous / minimally invasive spinal surgery. The Nerve Monitoring Cable includes a 1.5 mm female DIN connector for use with a stimulating console with a Type BF or CF rating. The other end of the Nerve Monitoring Cable includes a clip for connection to the stimulation accessories of this system. The stimulation accessories include general manual orthopedic surgical instruments previously cleared via K073227 (i.e. pedicle probes, taps, awls and screw drivers) and also include sterile/ single-use dilators which are subject of this submission. The subject dilators are a series of hollow tubes that fit over one another for the purpose of dilating tissue in preparation for spinal surgery. Similar to the predicate instrument accessories, they are made from a conducting metal (Aluminum 6061-T6) with an insulated outer coating (Parylene C) to allow passage of current from a point on the proximal end where it connects to the Nerve Monitoring Cable to an un-insulated portion of the distal tip. The purpose of this is to allow controlled monitoring of neural elements near and around the point of access. The subject dilators are offered sterile/single-use.
Intended Use:	The Nerve Monitoring Cable in conjunction with dilators, pedicle probes, taps, awls or screw drivers, are intended for tissue dilation/dissection and stimulation of peripheral nerves including spinal nerve roots for location and identification during spinal surgery. The dilators are also intended for use in surgical procedures to provide surgical access by dilating the soft tissue to the intended surgical site to allow passage of current from a point on the proximal end to an uninsulated portion of the distal tip. The purpose of this is to allow controlled monitoring of neural elements near and

<table>
<tr><td></td><td>around the point of access. The dilators are offered sterile/single use.</td></tr>
<tr><td>Technological Characteristics:</td><td>The subject dilators are substantially equivalent to the predicate devices in terms of design, function, principles of operation, technological characteristics, intended use, and performance.

As compared to the Biomet predicate, the subject dilators are similar in that they are a series of hollow tubes intended for tissue dilation and stimulation of nerves for neuromonitoring applications. They are made from metal with an insulated outer coating. Similar to the Biomet and Stryker predicates, the electrical signal is supplied via FDA cleared neuromonitoring systems attached to a clip or probe that is attached to the neuromonitoring contact zone on the proximal end. The electrical signal is then transferred to a point on the distal end which is uninsulated (minimum exposed surface area is SE to the predicate devices).</td></tr>
<tr><td>Materials:</td><td>The subject dilators are made from Aluminum 6061-T6 conforming to ASTM B221 with an insulated outer coating (Parylene C).</td></tr>
<tr><td>Biocompatibility:</td><td>Biocompatibility testing was conducted on the subject dilators in accordance with the testing recommendations in ISO 10993-1 (Biological Evaluation of Medical Devices Part 1: Evaluation and Testing). The test results are summarized in the table below:
<table>
<tr><th>Test</th><th>Results</th><th>Conclusion</th></tr>
<tr><td>Cytotoxicity</td><td>No evidence of cytotoxicity.</td><td>Non-cytotoxic</td></tr>
<tr><td>Irritation</td><td>No evidence of irritation.</td><td>Non-irritant</td></tr>
<tr><td>Sensitization</td><td>No evidence of sensitization.</td><td>Non-sensitizing</td></tr>
<tr><td>Systemic Toxicity</td><td>No evidence of toxicity.</td><td>Not systemically toxic</td></tr>
</table>
As shown in the table, biocompatibility testing found the subject dilators to be non-cytotoxic, non-irritant, non-sensitizing, and not systemically toxic.</td></tr>
<tr><td>Summary of Performance Data:</td><td>This 510(k) premarket notification is seeking clearance of subject dilators as accessory instruments during neuromonitoring applications. Performance testing and engineering calculations were performed to demonstrate that the subject devices are substantially equivalent to the identified predicates in terms of design, performance and intended use.

Engineering analysis confirmed the maximum charge, current, and power densities of the subject devices fall within the range of predicate devices. IEC 60601-1 testing for electrical safety on applicable devices of the subject system was supplied. A porcine animal study was conducted to assess the performance, functionality, and safety or the subject dilators as neuromonitoring accessory instruments. Electrical/resistance bench testing confirmed the subject dilators are capable of transferring an electrical current with little or no resistance in a similar manner to predicate devices. This bench testing, along with in-process Hipot testing, also confirmed the coating of each device provides adequate electrical insulation. Sterilization, packaging, and shelf-life validations were also completed per applicable test standards (ISO 11137-2, ISO 11607, and ASTM D4169 respectively).</td></tr>
</table>

	The performance data confirmed the substantial equivalence of the subject devices and demonstrates the subject devices are as safe, as effective, and perform as well as, or better than, the predicate devices.

Substantial Equivalence Summary - Comparison of Subject and Predicate Systems

Characteristic	Subject K142438 Nerve Monitoring Cable System	Predicate K073229 Nerve Monitoring Cable and Reusable Accessory Instruments	Predicate K132373 Biomet Spine Probes/ Guidewires and Dilators	Predicate K140400 ES2® Neuro-monitoring Accessory Instruments	Substantial Equivalence
Neuromonitoring Accessories Instruments	Dilators	General, manual orthopedic reusable surgical instruments (e.g. probes, awls, taps, inserters)	Probes, guidewires and dilators	Awls, Taps and Screwdriver to be used with Dilators or Tap Sleeves	Yes
Use of Dilators	Dilators	No dilators in K073229	Dilators	Dilators or Tap Sleeve	Yes
Compatible with Common Neuromonitoring Consoles & Software	Compatible with FDA cleared neuromonitoring systems	Compatible with FDA cleared neuromonitoring systems	Compatible with FDA cleared neuromonitoring systems	Compatible with FDA cleared neuromonitoring systems	Yes
Connection to Neuromonitoring Unit	Clip	Clip	Clip or Probe	Clip or Probe (based on Neuromonitoring System used)	Yes
Materials	ASTM B221 6061 Aluminum (UNS A96061) with Parylene C Coating	-ASTM F899 17-4 SST with Halar® 6014 Coating -Detachable silicone handles or RADEL ® handles	ASTM F899 Stainless steel with polymeric dielectric coating	-Awl, Taps, & Screwdriver: Surgical Grade Stainless Steel -Dilators & Tap Sleeve: RADEL®	Yes
Indications for Use	The Nerve Monitoring Cable in conjunction with dilators, pedicle probes, taps, awls or screw drivers, are intended for tissue dilation/ dissection and stimulation of peripheral nerves including spinal nerve roots for location and identification during spinal surgery. The dilators are also intended for use in surgical procedures to provide surgical access by dilating the soft tissue to the intended surgical site to allow passage of current from a point	The Pioneer Nerve Monitoring Cable, in conjunction with Pioneer pedicle probes, taps, awls or screw drivers, is intended to stimulate peripheral motor nerves during surgery for the purpose of locating and identifying these nerves, including spinal nerve roots during the incision and removal of soft and hard tissue or bone.	The Biomet probes/ guidewires and dilators are intended for tissue dilation and stimulation of peripheral nerves including spinal nerve roots for location and identification during spinal surgery.	The ES2® Awl, ES2® Taps, and ES2® Screwdriver can be used to assist in location of the spinal nerves by providing proximity information before, during or after bone preparation and placement of bone screws in open and percutaneous posterior surgical approaches of the non-cervical spine.	Yes – There are no new or different intended uses as compared to the predicates. The subject and predicate instruments are employed in the same manner when used for tissue dilation and as tools to assist the surgeon in locating spinal nerves before, during, or after surgery for open and

	on the proximal end to an uninsulated portion of the distal tip. The purpose of this is to allow controlled monitoring of neural elements near and around the point of access. The dilators are offered sterile/single use.				percutaneous surgical approaches.
Sterilization	Instruments provided as single-use sterile packed devices.	Neuromonitoring Clip provided as single-use sterile packed devices. Accessory instruments provided as reusable non-sterile devices with validated sterilization parameters to assure a SAL of 10^{-6}	Instruments provided as single-use sterile packed devices.	Instruments provided as reusable non-sterile devices with validated sterilization parameters to assure a SAL of 10^{-6}	Yes
Surgical Approach	Open or Percutaneous/ Minimally Invasive	None specified	None specified	Open or Percutaneous/ Minimally Invasive	Yes
Electromagnetic Compatibility & Electrical Safety	IEC 60601-1	IEC 60601-1	ASTM D149: 2009	IEC 60601-1 IEC 60601-1-2 IEC 60601-3-2 IEC 60601-3-3	Yes – Subject system compliant with applicable sections of IEC 60601-1.
Min. exposed surface area during tissue stimulation	0.02 in^2	0.02 in^2	.167 cm2 (.026 in2)	0.53 mm^2 (.0008 in^2)	Yes
Maximum Charge Density ($\mu C/cm^2$)	0.108	N/A	0.097	0.306	Yes
Maximum Current Density (mA/cm^2)	1.080	N/A	0.970	3.057	Yes
Maximum Power Density (500 Ω load) (mW/cm^2)	0.087	N/A	0.079	0.248	Yes
Maximum Power Density (10kΩ load) (mW/cm^2)	1.750	N/A	1.571	4.952	Yes

Conclusion:	Based on the information included in this premarket notification, the subject system is substantially equivalent to the predicates. The subject dilators are employed in the same manner, have similar intended uses, principles of operation, technological characteristics, and performance. There are no new issues of safety or efficacy.